

**REMARKS**

With entry of this Amendment, claims 1-83 are pending in the application. Claims 68-83 have been withdrawn from consideration in view of a Restriction Requirement. By this amendment claims 56 and 63 have been amended for clarity in accordance with the Examiner's suggestions. Also by this submission, the specification has been amended to expand the priority claim in the application to embrace earlier parental filings. All of the amendments presented herein are fully supported by the disclosure and no new matter has been added to the application.

**Affirmation of Restriction/Election**

Applicants note that a Restriction Requirement was made in the application calling for election to one of the following inventions.

I. Claims 1-67, drawn to an isolated infectious human-bovine chimeric parainfluenza virus, a method for stimulating the immune system of an individual and an immunogenic composition to elicit an immune response against PIV, classified in class 424, subclass 184.1.

II. Claims 68-80, drawn to an isolated polynucleotide, classified in class 514, subclass 44.

III. Claims 81-83, drawn to a method and vector for producing an infectious attenuated chimeric PIV particle, classified in class 435, subclass 69.1.

During a telephone conversation with Jeffrey King on. Affirmation of this election must be made by applicant in replying to this Office action. Claims 68-83 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicants' representative, Jeffrey King, made a provisional election on May 25, 2001 to prosecute the invention of Group I, claims 1-67. Applicants hereby affirm this election. This election is made without prejudice, in that Applicants do not accede to the merits of the Restriction Requirement. On the contrary, the issues raised in the Restriction Requirement are rendered moot by this election, and no representations are made by Applicants as to the possible existence, or non-existence, of separate and/or

distinct inventions presented in the original claims in relation to the separate inventive groups proposed by the Office.

### Drawings

Applicants acknowledge the Draftperson's objections to the drawings. Formal drawings will be filed in due course in the application to obviate these objections.

### Specification

The specification is objected on the stated basis that "references to amino acids positions must be accompanied by corresponding SEQ ID NO. The Office refers for example to page 15 of the specification as requiring appropriate correction.

Applicants respectfully submit that the specification and claims are in full compliance with the Sequence Rules. In particular, all sequences of four or more amino acids and all unbranched sequences of ten or more nucleotides have been appropriately assigned SEQ ID NO.s. The page of the disclosure to which the Office refers sets forth identifications of specific, single amino acids by positional reference, e.g., "Tyr<sub>942</sub>". In accordance with 37 CFR § 1.821, identification of individual amino acids or nucleotides in the specification, such as by the designation "Tyr<sub>942</sub>", does not invoke a requirement for inclusion of these designates in a separate Sequence Listing. Similarly, in accordance with 37 CFR § 1.821(d), identification of individual amino acids or nucleotides in the claims does not appear to invoke a requirement for use of the identifier "SEQ ID NO:" in the text of the claims. On the contrary, this requirement appears to only arise when the claims recite "a sequence that is set forth in the 'Sequence Listing' . . . ."

Applicants' references to individual nucleotides and amino acids in the specification and claims as noted by the Office are therefore in full compliance with the Sequence Rules. Notably, these references to individual nucleotides and amino acids need not be specifically correlated to sequences set forth in the application Sequence Listing, but may instead be correlated by reference to sequences provided in priority patent applications and/or publications incorporated by reference in the disclosure and/or constituting sequence information that is widely known in the art and therefore not necessary to incorporate in the disclosure.

In view of the foregoing, withdrawal of the stated objections to the specification for alleged non-compliance with the Sequence Rules is earnestly solicited.

Patentability Under 35 USC § 112

Claims 56-57 and 63-67 are rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically the Office objects to the use of the term “The chimeric PIV of claim 1 which is a virus” in claim 57, stating that the term is allegedly redundant in a claim to a parainfluenza virus. In claim 57, the term “subviral particle” is objected to as allegedly unclear.

To obviate the foregoing grounds of rejection, Applicants have amended the subject claim 56 herein to clarify that the claim is now drawn to “chimeric PIV of claim 1 which is a complete virus”. As is clearly denoted in the specification and original claims, the PIV of claim 1 is directed to an isolated infectious viral particle that comprises at a minimum the N, P and L proteins. This basic “virus” of the invention is an incomplete, yet viable, infectious and immunogenic viral particle. Of course, a variety of infectious viruses are provided within the invention that are viable and infectious without the inclusion of “non-essential” components found in a “complete” PIV. In contrast, as is also disclosed in the specification, it is within the scope of the invention to provide recombinant PIV that comprise essentially complete viruses, i.e., with all essential viral components and further including non-essential components as found in a complete, e.g., wild-type, PIV. Clearly representative of these teachings, the specification teaches that a number of non-essential genes can be ablated or otherwise modified in a chimeric PIV of the invention to yield desired effects on virulence, pathogenesis, immunogenicity, and other phenotypic characters, for example, ablation by deletion of a non-essential ORF such as C, D or V,

In view of the foregoing clarifying amendment and comments, the rejections of claim 56, amended to recite a “complete virus”, and of claim 57, properly reciting a “subviral particle” is believed to be obviated.

The Office has rejected claim 63 and dependent claims 64-67 for reciting an “immunogenically sufficient amount”, which term is alleged to be unclear. The Office

suggests introduction of a clarifying term “such as eliciting antibodies.” Applicants have followed the Office’s suggestion by introduction of the term “to elicit PIV virus neutralizing antibodies”, as supported in the specification, e.g., at page 1, lines 32-33. Withdrawal of the rejection of claims 63-67 under 35 U.S.C. 112, second paragraph is therefore respectfully requested.

#### Patentability Under 35 USC § 103

Claims 1-67 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Murphy et al (WO 98/53078). Applicants respectfully traverse. Without addressing the stated grounds for rejection or acceding to their merits, it is noted that the rejection is clearly obviated by the amendment herein amending the priority claim of the application.

The present application has now been related back in its priority through the entire foundational lineage that includes the priority U.S. provisional and regular filings on which the Murphy et al. WO 98/53078 published PCT application was based. Based on this revised priority, the Murphy et al. WO 98/53078 publication does not serve as prior art to support the rejection of claims as currently levied by the Office. To the extent that the Murphy et al. WO 98/53078 publication teaches aspects of the instantly claimed invention, those aspects are fully disclosed in the above-identified earlier-filed priority applications.

For the foregoing reasons, withdrawal of the rejection of claims 1-67 under 35 U.S.C. 103(a) as allegedly unpatentable over Murphy et al (WO 98/53078) is earnestly solicited.

#### **CONCLUSION**

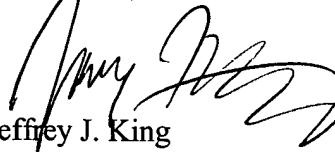
In view of the foregoing, Applicants believe that all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 206-332-1380.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned **"Version with markings to show changes made."**

Date: **January 3, 2002**

Respectfully submitted,



Jeffrey J. King  
Registration No. 38,515

WOODCOCK WASHBURN LLP  
One Liberty Place - 46th Floor  
Philadelphia, PA 19103  
Telephone: (215) 568-3100  
Facsimile: (215) 568-3439

**VERSION WITH MARKINGS TO SHOW CHANGES MADE****IN THE SPECIFICATION**

--At page 1, in the section entitled "CROSS-REFERENCES TO RELATED APPLICATIONS", following lines 6-7, please add the following amended priority claim in the application. --The present application also claims the priority benefit of, and is a continuation-in-part of, U.S. Patent Application No. 09/083,793, filed May 22, 1998, which in turn confers priority claimed herein from U.S. Provisional Application No. 60/047,575, filed May 23, 1997 (now abandoned), and U.S. Provisional Application No. 60/059,385, filed September 19, 1997 (now abandoned). The disclosure of each of the foregoing priority applications is incorporated herein by reference.--

**IN THE CLAIMS:**

Please amend the claims as follows:

56. (Amended) The chimeric PIV of claim 1 which is a complete virus.

**IN THE SPECIFICATION**

--At page 1, in the section entitled "CROSS-REFERENCES TO RELATED APPLICATIONS", following lines 6-7, please add the following amended priority claim in the application. --The present application also claims the priority benefit of, and is a continuation-in-part of, U.S. Patent Application No. 09/083,793, filed May 22, 1998, which in turn confers priority claimed herein from U.S. Provisional Application No. 60/047,575, filed May 23, 1997 (now abandoned), and U.S. Provisional Application No. 60/059,385, filed September 19, 1997 (now abandoned). The disclosure of each of the foregoing priority applications is incorporated herein by reference.--

**IN THE CLAIMS:**

Please amend the claims as follows:

56. (Amended) The chimeric PIV of claim 1 which is a complete virus.

63. (Amended) An immunogenic composition to elicit an immune response against PIV comprising an immunogenically sufficient amount of the chimeric PIV of claim 1 in a physiologically acceptable carrier to elicit PIV virus neutralizing antibodies.